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| 09/721,462 | 11/22/2000 | Adnan Shennib | 022176-001522US | 3046 |

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| EXAMINER | |
|---|---|
| FAULK, DEVONA E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 2615 | |

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/721,462 | SHENNIB, ADNAN | |
| | Examiner | Art Unit | |
| | Devona E. Faulk | 2615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/22/2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments filed 6/30/2006 have been fully considered but they are not persuasive.

Regarding claims 1,13, and 25 the applicant asserts that prior art Heartl is not directed to an intracanal shield shaped and dimensioned to be laterally positioned with respect to said hearing device so that the intracanal shield caps the cavity of said ear canal. The examiner asserts that Heartl was cited for disclosing an intracanal shield for positioning entirely in the ear canal (12, Figure 1; column 3, lines 7-34; reads on acoustically permeative cap of claim 25) comprising: a central porous member (14, Figures 4-15) having pores sized for allowing air to pass through (column 3, lines 10-25), said intracanal shield (Figures 4-11; column 3,lines 20-33; column 4, lines 1-25), when fitted in said retaining manner in the ear canal cavity, being positioned laterally with respect to a miniature hearing device medially positioned in close proximity to the eardrum, whereby to protect said hearing device against penetration of fluids and debris through said porous member while allowing air-borne sounds to reach said hearing device (column 3, lines 10-20).

The examiner noted that Haertl failed to disclose that the shield is positioned entirely in the ear canal and capping the cavity of said ear canal, that said porous member prevents passage of fluids and solids therethrough and has a conforming perimeter for fitting in a retaining manner along the cross sectional wall of the ear canal.

The examiner cited prior art Williams for disclosing a shield (earplug) capping the cavity of the ear canal and having a conforming perimeter (Figure 1) for fitting in a retaining manner along the cross sectional wall of the ear canal and a porous member preventing passage of fluids and solids (column 1,lines 22-25 and 35-38; column 4,lines 35-41).

The applicant also asserts that Haertl teaches away from a conformable perimeter in that Haertl teaches that its cap is sufficiently right to screw or snap onto an opening of the hearing aid (column 3, lines 5-10). The examiner asserts that column 3, lines 5-10 recites that the cap (12) is a screwable cap but it does not teach that the cap is rigid. The applicant does not supply any evidence as to how screwable equates to rigid and asserts that it is not implicit that because a cap is screwable that it is rigid.

Additionally, the hardness of polytetrafluorethylene decreases with increasing temperature.

Furthermore, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

2. The examiner is maintaining the rejection.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. **Claims 1-8 and 25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Haertl (U.S. Patent 4,987,597) in view of Williams (US 5,573,015) in view of Adams (US 5,488,961).

Regarding **claims 1 and 25**, Haertl discloses an intracanal shield for positioning entirely in the ear canal (12, Figure 1; column 3, lines 7-34; reads on acoustically permeative cap of claim 25) comprising:

a central porous member (14, Figures 4-15) having pores sized for allowing air to pass through (column 3, lines 10-25),

said intracanal shield (Figures 4-11; column 3,lines 20-33; column 4, lines 1-25), when fitted in said retaining manner in the ear canal cavity, being positioned laterally with respect to a miniature hearing device medially positioned in close proximity to the eardrum, whereby to protect said hearing device against penetration of fluids and debris through said porous member while allowing air-borne sounds to reach said hearing device (column 3, lines 10-20).

Haertl fails to disclose that the shield is positioned entirely in the ear canal and capping the cavity of said ear canal, that said porous member prevents passage of

fluids and solids therethrough and has a conforming perimeter for fitting in a retaining manner along the cross sectional wall of the ear canal.

Williams discloses a shield (earplug) capping the cavity of the ear canal and having a conforming perimeter (Figure 1) for fitting in a retaining manner along the cross sectional wall of the ear canal and a porous member preventing passage of fluids and solids (column 1,lines 22-25 and 35-38; column 4,lines 35-41).

It would have been obvious to modify Haertl so that the shield is separate from the hearing, having the ability to conform to the ear canal of the user in order to provide protect the entry of the ear canal from entry of foreign matter into the ear canal (Williams, column 3, lines 23-25)

Haertl as modified teaches that the porous member is air permeable (Haertl, column 3, line 32; reads on providing a circulated air flow of claims 1 and 25) . Haertl as modified to disclose that this helps reduce infection .

Haertl fails to disclose that air circulation can prevent infection . Adams teaches of allowing air circulation and blocking water and water and other contaiminatns. This would implicitly prevent infection(column 4, lines 58-66)(reads on air circulation sufficient to reduce an incidence of infection of claims 1 and 25). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Haertl by using the concept of air circulation reducing infection as taught by Adams in order to reduce the probably of infection to the wearer of the device.

Regarding **claim 2,** Haertl as modified by Williams and Adams discloses wherein said intracanal shield is separate from said canal hearing device for independent

insertion and removal while said hearing device is positioned in-situ. Williams's earplug reads on separate shield (see above apropos rejection of claim 1).

Regarding **claim 3,** Haertl as modified by Williams and Adams discloses wherein said intracanal shield is attached to said canal hearing device for insertion into and removal from said ear canal along with hearing device (Haertl, column 3, lines 8-10).

Regarding **claims 4-6,** Haertl as modified by Williams and Adams discloses wherein said porous member is hydrophobic, oleophobic and comprises a porous membrane (Haertl, column 2, line 1; column 3, lines 10-20).

Regarding **claim 7,** Haertl as modified by Williams and Adams discloses wherein said intracanal shield is composed of disposable material for cost-effective single use of said shield. Williams teaches of disposable earplugs (column 7, lines 13-14). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to have the shield be composed of a disposable material for the benefit of having a shield that is more easily replaced.

Regarding **claim 8,** Haertl as modified by Williams and Adams discloses but Brown teaches of wherein said shield is at least partially composed of polyurethane foam (Williams, column 4, lines 39-40).

5. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Haertl (U.S. Patent 4,987,597) in view of Williams (US 5,573,015) in view of Adams (US 5,488,961) in further view of Anderson (US 5,238,613).

Regarding **claim 10,** Haertl as modified by Williams and Finlayson fail to disclose wherein pores are sized in the range of 1 to 10 microns. Anderson teaches wherein pores are sized in the range of 1 to 10 microns (abstract). It would have been obvious to modify Haertl as modified by Finlayson by having the pores sized between 1 and 10 microns as taught by Anderson in order to have a high porous membrane that is liquid-impermeable(abstract).

6. **Claims 9,11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Haertl (U.S. Patent 4,987,597) in view of Williams (US 5,573,015) in view of Adams (US 5,488,961) in further view of Brown et al. (U.S Patent 6,129,174).

Regarding **claim 9,** Haertl as modified by Williams and Adams fail to disclose wherein said shield is at least partially composed of silicone material. Brown teaches on a replaceable acoustic coupler , including a cerumen-protecting feature (Abstract), made of a compressible material, such as polyurethane foam or silicone, to conform to the shape of ear canal, thus sealing the ear canal (column 7, lines 7-15). Thus it would have been obvious to one of ordinary skill in the art to have the shield at least partially composed of silicone for the benefit of enabling the intracanal device to better conform to the shape of ear canal, thus sealing the ear canal.

Regarding **claim 11,** Haertl as modified by Williams and Adams fails to explicitly disclose wherein said intracanal shield is shaped and dimensioned to be positioned deep in the ear canal past the hair and cerumen production area therein. Brown discloses a replaceable acoustic coupler, including a cerumen-protecting feature (Abstract), adapted for use with an intracanal receiver module can be deeply inserted

into the ear canal of the user while making minimal contact with the walls of the ear canal (See Abstract). Therefore, the concept of having an intracanal device that can be deeply inserted in the ear canal was well known at the time of filing. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use Brown's concept of deeply inserting an intracanal shield so that it could be inserted deeply into the ear for the benefit of enabling a deeper insertion of the hearing aid.

7. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Haertl (U.S. Patent 4,987,597) in view of Williams (US 5,573,015) in view of Adams (US 5,488,961) in further view of Oliveira (U.S. Patent 5,401,920).

Regarding **claim 12,** Haertl as modified by Williams and Adams fails to disclose wherein said intracanal shield has an oval cross-sectional shape adapted to fit comfortably in a cross section of the ear canal. Oliveira discloses the concept of an intracanal shield having an oval cross-sectional shape (Figure 1). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use Oliveira's concept of an intracanal shield having an oval cross-sectional shape in order to better conform better to a device.

8. **Claims 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Haertl (U.S. Patent 4,987,597) in view of Williams (US 5,573,015) .

Regarding **claim 13**, Haertl discloses a hearing system (Figure 1) fabricated and adapted to be positioned entirely in the ear canal for extended wear (12, Figure 1; column 3, lines 7-34), comprising:

a hearing device (Figure 1) assembled and dimensioned to be medially positioned in the ear canal and

an intracanal shield (12, Figure 1; column 3, lines 20-33) shaped and dimensioned to be laterally positioned with respect to said hearing device, comprising:

a central porous member (14, Figures 4-15) for air ventilation with respect to said hearing device, and having pores (column 3, lines 10-25).

Haertl fails to disclose that the shield caps the cavity of said ear canal, that said porous member prevents passage of fluids and solids therethrough and has a conforming perimeter for fitting in a retaining manner along the cross sectional wall of the ear canal.

Williams discloses a shield (earplug) capping the cavity of the ear canal and having a conforming perimeter (Figure 1) for fitting in a retaining manner along the cross sectional wall of the ear canal and a porous member preventing passage of fluids and solids (column 1,lines 22-25 and 35-38; column 4,lines 35-41).

It would have been obvious to modify Haertl so that the shield is separate from the hearing, having the ability to conform to the ear canal of the user in order to provide protect the entry of the ear canal from entry of foreign matter into the ear canal (Williams, column 3, lines 23-25)

Regarding **claim 14,** Haertl as modified by Williams discloses wherein said intracanal shield is separate from said hearing device for independent insertion into and removal from the ear while said hearing device is positioned in-situ Williams earplug reads on separate shield (see above apropos rejection of claim 13).

Regarding **claim 15,** Haertl as modified by Williams discloses wherein said intracanal shield is attached to said canal hearing device for insertion into and removal from said ear canal along with hearing device (Haertl, column 3, lines 8-10).

Regarding **claims 16-18,** Haertl as modified by Williams disclose wherein said porous member is hydrophobic, oleophobic and comprises a porous membrane ((column 2, line 1; column 3, lines 10-20).

Regarding **claim 19,** Haertl as modified by Williams discloses wherein said intracanal shield is disposable. Williams teaches of disposable earplugs (column 7, lines 13-14). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to have the shield be composed of a disposable material for the benefit of having a shield that is more easily replaced.

Regarding **claim 20,** Haertl as modified by Williams discloses but Brown teaches of wherein said shield is at least partially composed of polyurethane foam (Williams, column 4, lines 39-40).

9. **Claim 22** is rejected under 35 U.S.C. 103(a) as being unpatentable over Haertl (U.S. Patent 4,987,597) in view of Williams (US 5,573,015) in further view of Anderson (US 5,238,613).

Regarding **claim 22,** Haertl as modified by Williams and Finlayson fail to disclose wherein pores are sized in the range of 1 to 10 microns. Anderson teaches wherein pores are sized in the range of 1 to 10 microns (abstract). It would have been obvious to modify Haertl as modified by Finlayson by having the pores sized between 1 and 10

microns as taught by Anderson in order to have a high porous membrane that is liquid-impermeable(abstract).

10. **Claim 24** is rejected under 35 U.S.C. 103(a) as being unpatentable over Haertl (U.S. Patent 4,987,597) in view of Williams (US 5,573,015) in further view of Oliveira (U.S. Patent 5,401,920).

Regarding **claim 24,** Haertl as modified by Williams fails to disclose but Oliveira teaches wherein said intracanal shield has an oval cross-sectional shape adapted to fit comfortably in a cross section of the ear canal. Oliveira discloses the concept of an intracanal shield having an oval cross-sectional shape (Figure 1). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use Oliveira's concept of an intracanal shield having an oval cross-sectional shape in order to better conform better to a device.

11. **Claims 21,23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Haertl (U.S. Patent 4,987,597) in view of Williams (US 5,573,015) in further view of Brown et al. (U.S Patent 6,129,174).

Regarding **claim 21,** Haertl as modified fails to disclose wherein said intracanal shield is at least partially composed of silicone material. Brown teaches on a replaceable acoustic coupler , including a cerumen-protecting feature (Abstract), made of a compressible material, such as polyurethane foam or silicone, to conform to the shape of ear canal, thus sealing the ear canal (column 7, lines 7-15). Thus it would have been obvious to one of ordinary skill in the art to have the shield at least partially

composed of silicone for the benefit of enabling the intracanal device to better conform to the shape of ear canal, thus sealing the ear canal.

Regarding **claim 23,** Haertl as modified fails to explicitly disclose wherein said shearing system is fabricated and dimensioned to be positioned deep in the ear canal past the hair and cerumen production area therein. Brown discloses a replaceable acoustic coupler, including a cerumen-protecting feature (Abstract), adapted for use with an intracanal receiver module can be deeply inserted into the ear canal of the user while making minimal contact with the walls of the ear canal (See Abstract). Therefore, the concept of having a intracanal device that can be deeply inserted in the ear canal was well known at the time of filing. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use Brown's concept of deeply inserting an intracanal shield so that it could be inserted deeply into the ear for the benefit of enabling a deeper insertion of the hearing aid.

## *Conclusion*

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Devona E. Faulk whose telephone number is 571-272-7515. The examiner can normally be reached on 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vivian Chin can be reached on 571-272-7848.

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 2615. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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